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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/630,383	04/10/1996	PHILIPPE POULETTY	A-55320-2/BI	3596

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/630,383	Applicant(s) POULETTY, PHILIPPE	
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22 is/are pending in the application.
 4a) Of the above claim(s) 18,21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-17,19,20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/2004 has been entered.

2. Regarding priority for the claimed invention and the application of prior art, the claimed invention using folate is not disclosed in the parent applications to which priority is claimed and therefore the priority date for application of prior art is the filing date of the instant application.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14-17,19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "other than an antibody or fragment thereof" in claims 14 and 19. Applicant has not indicated where said limitation finds support in the specification as originally filed. Said limitation is not disclosed in the specification as originally filed. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

5. Regarding the term "Gal α 1-3 Gal B1-4GlcNAc-R" and the definition of "R", while said letter is not defined in the specification, based on the prior art of record (such

as Galili, Immunology Today), it appears that R refers to any molecule to which the carbohydrate is attached. Therefore, an antibody containing the aforementioned carbohydrate would be encompassed by "Gal α 1-3 Gal B1-4GlcNAc-R".

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Kranz et al.(US Patent 5,547,668) as evidenced by Borrebaeck et al. Kranz et al. teach therapeutic conjugates containing folate covalently joined to a murine antibody (see column 4, third paragraph and column 7). Borrebaeck et al. disclose that the art recognized that murine antibodies contain alpha Gal which is bound by human anti alpha Gal antibodies(see page 477, second column). Thus, it is an inherent property of the conjugates taught by Kranz et al. that they contain the alpha Gal/ alpha galactosyl epitope. As per above, an antibody containing the aforementioned carbohydrate would be encompassed by "Gal α 1-3 Gal B1-4GlcNAc-R".

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).


9. Claims 14-17,19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pouletty (EP 0510949) in view of Kranz et al.(US Patent 5,547,668) ,Galili and prior art disclosed in the specification, page 10, lines 1-5.

Pouletty teaches a conjugate containing a target binding moiety and a selective moiety capable of binding to preformed antibodies (see claim 1). Pouletty et al. teach that the selective moiety can be an antigen to which natural antibodies exist (see column 3, last paragraph). Pouletty do not teach that the conjugate contains folate attached to "Gal α 1-3 Gal B1-4GlcNAc-R". Kranz et al. teach therapeutic conjugates containing folate, wherein the folate targets the conjugate to folate receptor positive tumor cells (see abstract). Galili teaches that "Gal α 1-3 Gal B1-4GlcNAc-R" is an epitope that binds natural antibodies found in humans wherein the natural antibodies are found in high concentrations in humans (see abstract). The specification discloses that methods for making "Gal α 1-3 Gal B1-4GlcNAc-R" conjugates were well known in the art (see page 10, lines 1-5). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Pouletty teaches a conjugate containing a target binding moiety and a selective moiety capable of binding to preformed antibodies whilst Kranz et al. teach therapeutic conjugates containing folate, wherein the folate targets the conjugate to folate receptor positive tumor cells and Galili teaches that "Gal α 1-3 Gal B1-4GlcNAc-R" is an epitope that binds natural antibodies found in humans wherein the natural antibodies are found in high concentrations in humans. One of ordinary skill in the art would have been motivated to make the claimed invention because Pouletty et al. teach that the selective moiety can be an antigen to which natural antibodies exist whilst Galili teaches that "Gal α 1-3 Gal B1-4GlcNAc-R" is an epitope that binds natural antibodies found in humans wherein the natural antibodies are found in high concentrations in

humans. One of ordinary skill in the art would have also been motivated to make the claimed invention because Kranz et al. teach therapeutic conjugates containing folate, wherein the folate targets the conjugate to folate receptor positive tumor cells.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday through Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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